



Anesthetic efficacy of single buccal infiltration of 4% articaine compared to routine inferior alveolar nerve block with 2% lidocaine during bilateral extraction of mandibular primary molars: a randomized controlled trial

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Background: Inferior alveolar nerve block (IANB) using lidocaine 2% is commonly used for anesthetizing primary mandibular molars; however, this technique has the highest level of patient discomfort compared to other local anesthesia techniques. Therefore, alternative anesthesia techniques are necessary. The aim of this study was to evaluate the efficacy of a single buccal infiltration of 4% articaine with IANB using 2% lidocaine, for the bilateral extraction of primary mandibular molars.

Methods: The present study was conducted on 30 patients aged between 6 and 9 years, who required the extraction of bilateral primary mandibular molars. The patients were randomly divided into two groups as follows: In the first session, Group A received IANB with lidocaine 2% and group B received infiltration with articaine 4%. In the second session, another injection method was performed on the opposite side. The Wong-Baker Facial Pain scale (WBFPS), Face Leg Activity Cry, and Consolability (FLACC), and physiologic parameters were used to assess pain perception.

Results: The independent t-test showed no statistically significant difference in blood pressure and heart rate before and after extraction ($P > 0.05$). The mean FLACC index in the lidocaine and articaine groups was 0.89 and 1.36, respectively; there was no statistically significant difference between them ($P > 0.05$). According to the results of the chi-square test, there was no statistically significant difference between the groups for WBFPS ($P > 0.05$).

Conclusion: The articaine infiltration technique may be an alternative to the IANB for the extraction of primary mandibular molars.

Keywords: Articaine; Buccal Infiltration; Children; Lidocaine; Tooth Extraction.

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INTRODUCTION

Tooth extraction is an invasive procedure, during which pain control is important for children's behavioral guidance as well as for alleviating anxiety. Local anesthetic drugs

are commonly used for achieving this pain control. Although local anesthetic injections stimulate pain and anxiety and have a negative response in children, they are used to attract their cooperation and comfort by delivering painless treatment. Therefore, dentists should always strive to help children cope with dental injections

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using a variety of anesthesia techniques and solutions [1,2].

Multiple techniques have been introduced to eliminate pain and discomfort during local anesthetic injections, including a computerized injection system, precooling the injection site, warming or buffering the local anesthetic solutions, and vibration or pressure to the injection site. However, there is no comprehensive agreement on the best technique. Davoudi A et al., in their brief review of these techniques, compared each one of the techniques with each other and recommended more clinical trials for a definite conclusion [3,4].

Lidocaine hydrochloride is an amide local anesthetic with a pH of about 3.5. It is metabolized to monoethylglycine and xylydide in the liver by microsomal oxidases. Since 1948, lidoaine HCL has been the first and most common local anesthetic drug employed in dentistry, and is considered the gold standard because of its acceptable performance in most situations and rare side effects and toxicity [5].

The inferior alveolar nerve block (IANB) is commonly used to anesthetize primary mandibular molars. Its main advantage is anesthesia over a large area. However, it has the highest level of patient discomfort compared to other local anesthesia techniques, causing a negative impact on the child's behavior. Also, there is a possibility of damage to the anesthetized tissues by lip-biting and resultant ulcers, especially in children [6]. The disadvantages of the IANB can be overcome by using less traumatic alternative techniques, such as infiltration, for anesthetizing primary mandibular molars [7].

Articaine hydrochloride is a relatively new amide local anesthetic approved by the US Food and Drug Administration in 2000 [8]. Due to its thiophene ring, it has high lipid solubility and therefore, a high ability to penetrate bone and soft tissue, making it more effective in infiltration injections [9]. Articaine has both ester and amide groups. Therefore, its biotransformation takes place in the plasma (hydrolysis by plasma esterase) as well as in the liver (by hepatic microsomal enzymes) and it has reduced toxicity. Articaine is available in 4% concentration

with 1: 100,000 or 1: 200,000 epinephrine [10].

Several studies have assessed the effectiveness of articaine as a local anesthetic and compared its features and benefits with those of lidocaine. The superiority of articaine in dental treatments has also been demonstrated [11].

However, studies have not achieved a comprehensive agreement on the efficacy of articaine over lidocaine for the extraction of primary molars. In 2018, Tong et al. performed a meta-analysis and reported significant discrepancies in the expression of results as well as a high risk of bias in children's studies. More accurate methodologies, including better standardization of reporting outcomes that provide less heterogeneous data for meta-analysis, are needed [12]. Tirupathi et al. performed a systematic review of the analgesic efficacy of a single buccal infiltration with 4% articaine for the extraction of primary molars in children and concluded that further evidence is required to justify this [13].

Therefore, the aim of this study was to evaluate and compare the anesthetic efficacy of a single buccal infiltration of 4% articaine with routine IANB using 2% lidocaine during the bilateral extraction of primary mandibular molars by subjective and objective pain assessment, as well as to compare physiological criteria to obtain valid and reliable pain measure parameters.

METHODS

1. Study design and participants

This single blind randomized controlled clinical trial had a crossover design, which was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences (ethics code: IR.SSU.REC.1398.103) and recorded on the Iranian Registry of Clinical Trials (IRCT20191004044977N1). The study was designed, conducted, and reported based on the spirit checklist [14].

Samples were collected from children referred to the pediatric department of the Faculty of Dentistry, Yazd Shahid Sadoughi University of Medical Sciences. Written

informed consent was obtained from the parents or legal guardians of the children who participated in the study after receiving a full explanation of the procedure and the circumstances that could lead to their child's withdrawal from the study.

2. Sample size determination

Considering the 95% confidence level, 80% power, a standard deviation of 2.8 for the pain score, and two units of difference between the two groups in changing the pain score, the size of each group was calculated to be 30. Thus, the total sample size was 60 teeth.

3. Sample selection

After obtaining the medical and dental history of 136 patients and conducting clinical and radiographic examinations on them, 30 children who met the inclusion criteria were included in the study.

Inclusion criteria:

- Medically healthy 6-9 year-olds, without allergies to drugs or local anesthetic solutions, and without learning disabilities
- Children who required bilateral mandibular primary molar extraction with at least one third of the root length remaining
- Cooperative children, with behavioral ratings of 3 or 4, according to the Frankl behavior classification scale
- Children with the ability to communicate in Persian

Exclusion criteria:

- Poor cooperation during treatment
- Teeth with acute abscess
- Taking analgesic before treatment
- Lack of complete anesthesia following the injection

4. Interventions

In the first session, an anesthesia procedure was randomly performed in a mandibular quadrant for each child. In the second session after two weeks, another procedure was performed on the opposite side. All

injections were administered by a pediatric dentistry resident.

First, the mucosa was dried with sterile gauze and a topical anesthetic was applied to reduce the discomfort associated with the insertion of the needle into the mucous membrane. Benzocaine gel 20% (Master-Dent, Dentonics Inc., Tophill Road, Monroe, USA) was applied and left in place for one minute. Then, either the buccal articaine infiltration or the lidocaine block was administered randomly. The injection rate was standardized to ~1 ml/min for both the groups [15]. The anesthetic solution in both groups was delivered using a dental syringe and a 15 mm long 27-gauge needle.

For articaine infiltration, 1.8 ml of 4% articaine hydrochloride with epinephrine 1: 100,000 (Dentacain 200, Exir Pharmaceutical Co., Boroojerd, Iran) was administered in the mucobuccal fold between the buccal roots of the mandibular primary molar under treatment. 1.8 ml lidocaine hydrochloride 2% with epinephrine 1: 100,000 (Persocaine-E, Darou Pakhsh, Tehran, Iran) was used for the IANB.

The symptoms of soft tissue anesthesia were evaluated by a dental scaler 10 minutes after articaine infiltration and 15 minutes after lidocaine block; treatment was initiated if anesthesia seemed sufficient. If the child reported any symptoms of pain or discomfort, treatment was stopped, supplemental PDL injection or conventional IANB was administered, and the tooth was extracted and excluded from the study. Positive reinforcement, tell-show-do, non-verbal behavior guidance, and verbal distraction were used as behavioral guidance techniques during anesthesia and tooth extraction at both visits.

The Wong Baker Facial Pain Scale (WBFPS), which is a self-report pain measure scale, was used to perform subjective evaluation after extraction [16]. Before starting any dental procedure, the WBFPS was explained to the child by a dentist. The child was shown a set of six cartoon faces with varying facial expressions ranging from a smile/laughter to tears, and was asked to choose the facial expression that best represented his/her experience. Each face was given a number from 1-10.

For objective evaluation, the Face, Legs, Activity, Cry, Consolability scale (FLACC), which is a valid and reliable criterion for children aged ≥ 1 year, was used. Each parameter of the five categories was scored from 0-2 within a total score ranging from 0-10 [17].

Before the injection of the anesthetic and after extraction, physiologic parameters, such as the patient's blood pressure and pulse rate, were measured using a digital sphygmomanometer (Omron M6 Comfort Blood Pressure Monitor, Omron Corp, Kyoto, Japan). The blood pressure cuff was attached to the left forearm of the child. Anesthetic efficacy was evaluated by comparing the results of these parameters for both techniques.

5. Randomization, concealed random allocation

Participants were allocated to the LA technique group (IANB or BI) and then to the side of tooth extraction. The anesthesia technique used in the first session was determined using a random list prepared by a statistician not involved in patient recruitment or assessments, using simple randomization with a sequence of 30 (A: lidocaine or B: articaine). The tooth extraction side was determined in the first session using a random list of 30 sequences with a block size of two (AB or BA) to determine which side of the mandible would be the test side and which the control (A: right molar or B: left molar). For allocation concealment, the sequences of both lists were written separately on cards and placed in sealed opaque envelopes placed in two separate boxes. The patient chose one envelope from each box.

6. Blinding

Local anesthesia was administered and the tooth was extracted by a dentist not blinded to the type of intervention. A second dentist, who was blinded to the type of intervention, evaluated the indices. As the patient could differentiate between infiltration and nerve block, the study was performed as a single blind trial.

7. Statistical analysis

Data was analyzed using SPSS 22 (SPSS Inc., Chicago

IL, USA). Intergroup comparisons of pulse rate and blood pressure were performed using the independent-sample t-test, and intragroup comparisons at two different time intervals were performed using the paired t-test. Intergroup comparisons of WBFPS and FLACC were performed using the chi-square and Mann-Whitney tests.

RESULTS

1. Participant characteristics

Thirty children were included in the study after examining 136 children aged 6-9 years, who were referred to the pediatric dentistry clinic of Shahid Sadoughi University of Medical Sciences between January and June 2020. Two children were excluded because they did not participate in the second treatment session. Thus, 28 children completed the study, of which 12 were female (42.8%) and 16 male (57.14%). A flow diagram summarizing the progress of the subjects through the clinical trial is presented in Figure 1. Of the 56 mandibular primary molars, 30 were first molars and 26 were second molars.

2. Physiologic parameters

The mean \pm SD systolic blood pressure in the lidocaine group before and after tooth extraction was 96.79 ± 12.384 mmHg and 105.18 ± 13.419 mmHg, respectively. In the articaine group, these values were 96.39 ± 12.276 mmHg and 104.46 ± 12.764 mmHg, respectively. The mean \pm SD diastolic blood pressure in the lidocaine group before and after tooth extraction was 69.43 ± 9.383 and 74.64 ± 11.298 , respectively. These values for the articaine group were 68.61 ± 8.816 and 72.64 ± 9.500 , respectively. Thus, the greatest difference between the two groups was seen in diastolic blood pressure after extraction. Application of the independent-sample t-test for these data showed no statistically significant difference in blood pressure between the lidocaine and articaine groups before injection and after extraction ($P > 0.05$) (Table 1).

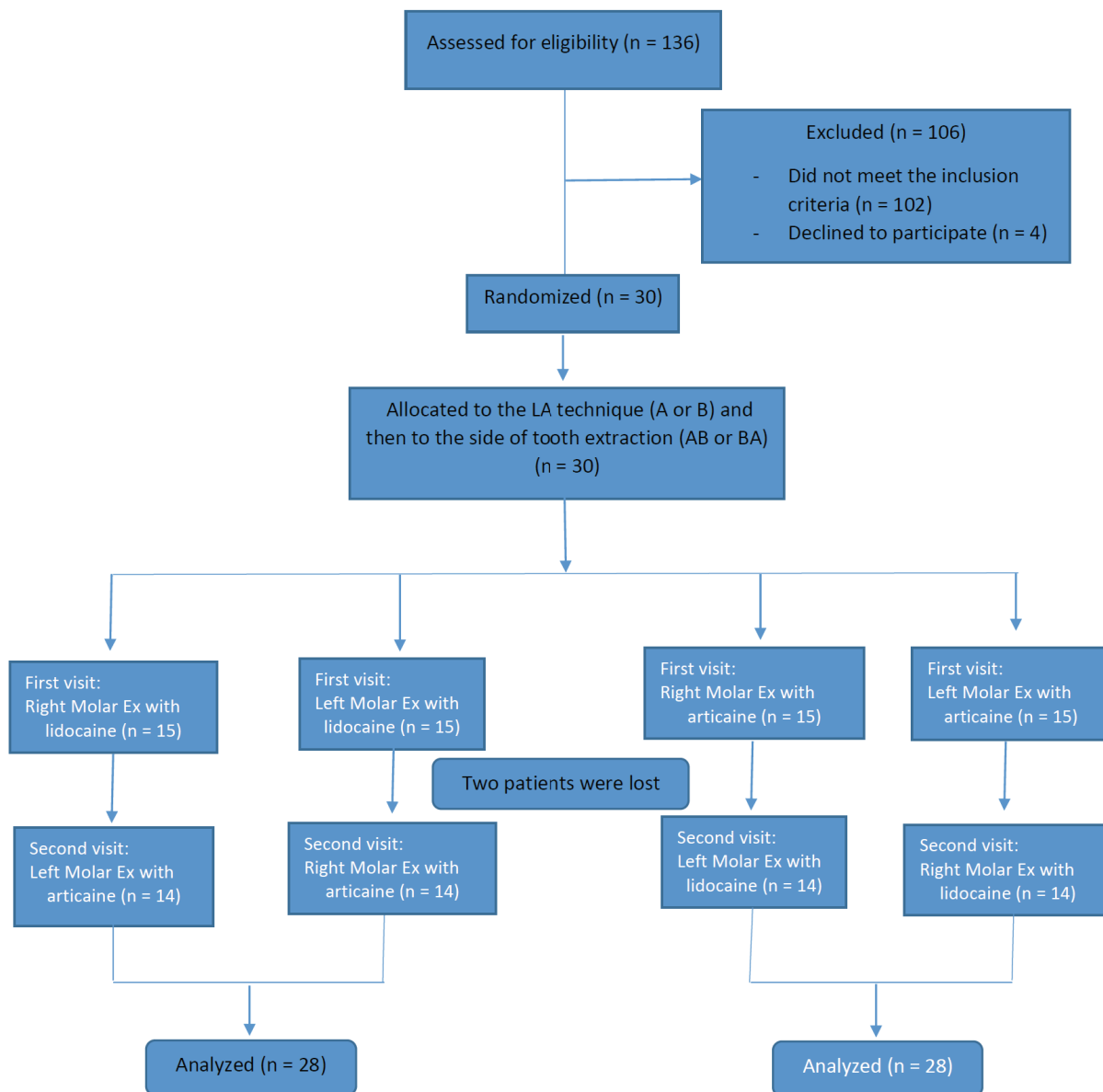


Fig. 1 Flow Chart of the Trial

Table 1. Blood pressure and pulse rate

Group (n)	Systolic BP, before injection (Mean ± SD)	Systolic BP, post extraction (Mean ± SD)	Diastolic BP, before injection (Mean ± SD)	Diastolic BP, post extraction (Mean ± SD)	Pulse Rate, before injection (Mean ± SD)	Pulse Rate, post extraction (Mean ± SD)
Lidocaine 2% IANB (28)	96.79 ± 12.384	105.18 ± 13.419	69.43 ± 9.383	68.61 ± 8.816	83.5 ± 12.273	85.21 ± 11.780
Articaine 4% BI (28)	96.39 ± 12.276	104.46 ± 12.764	74.64 ± 11.298	72.64 ± 9.500	93.79 ± 11.660	93 ± 12.956
P-value	0.863	0.456	0.799	0.931	0.734	0.686

IANB, inferior alveolar nerve block; BI, buccal infiltration; SD, standard deviation.

The mean ± SD pulse rate in the lidocaine group before injection and after extraction was 83.5 ± 12.273 and 85.21 ± 11.780 , respectively. In the articaine group, these values were 93.79 ± 11.660 and 93 ± 12.956 , respectively. The

t-test showed no statistically significant difference in mean pulse rate values between the two groups ($P > 0.05$) (Table 1).

Table 2. Face, Legs, Activity, Cry and Consolability (FLACC)

Group (n)	(Mean ± SD)	Sig.
Lidocaine 2% IANB (28)	0.89 ± 0.916	0.08
Articaine 4% BI (28)	1.36 ± 1.062	

IANB, inferior alveolar nerve block; BI, buccal infiltration; SD, standard deviation.

3. Objective parameter

The chi-square test revealed that the FLACC index in the lidocaine group had the highest frequency in scores 0 and 1 (equivalent to 39.3% for each). The highest frequency was seen in score 2 and score 3, respectively. In the articaine group, the highest frequency was seen in score 2 (equivalent to 37.5%), followed by scores 1 (28.6%) and 0 (25%). The mean FLACC index in the lidocaine and articaine groups was 0.89 and 1.36, respectively and the difference between the two groups was not statistically significant ($P > 0.05$) (Table 2).

4. Subjective parameter

For the WBFPS index in the lidocaine group, the highest frequency was seen in score 2 (60.7%), followed by scores 0 (28.5%) and 4 (10.7%). In the articaine group, the highest frequency was observed in score 4 (39.2%), followed by scores 2 and 0 (32.1% and 28.5%, respectively). The chi-square test revealed no statistically significant difference between the groups for WBFPS ($P > 0.05$) (Table 3).

DISCUSSION

Pain control during dental procedures, especially in children, is one of the most important factors for reducing fear and anxiety. Various studies have reported a strong association between pain and behavioral control problems [9,18].

There are three types of pain assessment tools: self-reporting, observation/behavioral, and physiologic measurement. It is important to choose an appropriate

Table 3. Wong-Baker Facial Pain scale (WBFPS)

Group (n)	(Mean ± SD)	Sig.
Lidocaine 2% IANB (28)	1.64 ± 1.224	0.15
Articaine 4% BI (28)	2.21 ± 1.663	

IANB, inferior alveolar nerve block; BI, buccal infiltration; SD, standard deviation.

scale depending on the child's developmental age. Since pain is a multidimensional phenomenon, more than one scale is required to assess pain [19,20].

According to a systematic review by Tomlinson et al., WBFPS is a quick and easy-to-use scale with psychometric properties needed to assess pain. When children are given a choice between face scales, they prefer the WBFPS [21]. The FLACC scale is one of the most common objective scales used to assess pain. There is credible evidence that the FLACC scale is a valid and reliable tool for pain measurement, suitable for assessing pain in infants, children, and adults, with the highest sensitivity and specificity at low scores [22,23]. To assess the physiological parameters of pain, blood pressure and heart rate, which are indirect measures of pain and anxiety not affected by the observer's opinion, were measured [24].

Therefore, in this study, we used all three types of pain assessment tools in the two groups, which led to the multidimensional evaluation of pain, providing more comprehensive results. So far, few studies, often related to the maxilla, have used all three tools to measure parameters [25,26].

In this study, although there was no statistically significant difference between the mean blood pressure and heart rate before and after tooth extraction in the two groups, the mean changes were higher in the lidocaine group. This may be due to the more painful injection of the block compared to infiltration, which increases the patient's anxiety. These results are in accordance with those of previous studies [8,9]. A study by Mittal et al., which evaluated the efficacy of lidocaine and articaine during the extraction of maxillary primary molars, also did not find a statistically significant difference in

physiological parameters [25]. Alinejhad et al. compared the efficacy of articaine infiltration and lidocaine block on the pulp therapy of primary mandibular second molars in children aged 6-8 and 8-10 years. They used the visual analog scale (VAS) to evaluate the pain during pulpotomy and found that it was significantly lower in the articaine group [27]. Varying results are seen due to the different methodologies and treatments compared with those described in this paper.

The WBFPS and FLACC index did not show a statistically significant difference between the two groups. These results are consistent with those of most existing studies that compared articaine infiltration and lidocaine block in children; no significant differences in anesthesia between the two techniques have been reported [8,28]. Given that these two techniques did not differ in terms of pain score and articaine infiltration without lingual injection is more comfortable for children, articaine infiltration could be suggested as an alternative to bilateral IANB.

Alzahrani et al. subjectively evaluated pain by comparing 4% articaine single buccal infiltration with 2% lignocaine IANB in children and suggested equivalence in success rates for both anesthetic techniques during treatment. This review had some limitations. It was done for different dental procedures, such as pulp therapies and extraction, which may affect the validity of the findings. They also did not evaluate physiologic parameters [28].

Arrow P et al. compared articaine 4% and lidocaine 2% in infiltration and block injections in pediatric restorative treatment. They found no statistically significant difference in the success of anesthesia between lidocaine and articaine by infiltration, but reported higher success and less pain in IANB with lidocaine. They stated that the higher success of block injections could be due to the higher skill of the clinicians participating in the study, who commonly used IANB for treatment in the posterior mandible [9]. Contrary to this, in our study, the mean scores of the objective and subjective indices of pain assessment were higher in the articaine infiltration injection group, although the difference between the

groups was not statistically significant. This may be due to variation in the penetration of anesthetic solution beyond the cortical bone and soft tissue with age, and the consequent difference in the degree of lingual tissue anesthesia, which is important during extraction. Various studies have estimated the success rate of articaine infiltration to be approximately 70% [9,29]. IANB injection is associated with greater discomfort, especially in children, due to the deeper insertion of the needle, and its success is estimated to be about 85% due to anatomical differences [30].

Since this was a cross-over design study, each child was considered to be self-controlled. After treatment, the indices were evaluated by the child and a clinician who was not aware of the type of anesthetic solution. For more accurate evaluation, further studies should be performed by evaluating the indices during injection and treatment.

One of the limitations of this study was the sample size. Only 30 children participated in the study. This number may not completely represent the community. The second limitation was related to the split-mouth design of the study, called the carry-over effect, which explains the long effect of a previous experiment on the current experiment. Two steps of randomization in the present study minimized this bias.

In conclusion, this study found that articaine 4% buccal infiltration injection was as effective as lidocaine 2% IANB for the extraction of primary mandibular molars, allowing clinicians to avoid the IANB in children.

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